Significant Analysis for
Rules Concerning
WAC 246-919-605 Use of Lasers, Light, Radiofrequency, and Plasma Devices by Physicians
WAC 246-918-125 Use of Lasers, Light, Radiofrequency, and Plasma Devices by Physician Assistants

Background

RCW 18.71 regulates the practice of medicine in Washington State by establishing the Medical Quality Assurance Commission (Commission). Under RCW 18.71.002, one of the purposes of the Commission is to regulate the competency and quality of professional health care providers under its jurisdiction by establishing consistent standards of practice. To do this, the Commission may develop rules that promote the delivery of quality health care to the residents of Washington State.

The Federal Food and Drug Administration (FDA) and state laws regulate the manufacture of certain medications because those medications are considered too dangerous to be available without the prescription of a licensed practitioner, and without certain restrictions on this prescribing. Similarly, the FDA regulates medical lasers and similar devices due to the risk of complications from their use. According to the FDA web site, medical lasers are prescription devices available for sale only to licensed practitioners with prescriptive authority as determined by state law. Complications from the use of lasers for skin care and treatment include visual impairment, blindness, inflammation, burns, scarring, hypopigmentation and hyperpigmentation. Yet, there is no state law regulating the use of such devices.

There are many offices and clinics in the state of Washington providing treatment with Lasers, Light, Radiofrequency, and Plasma devices. Some offices and clinics have a physician on site, some have a physician off-site, and some have no physician involvement at all. Some offices and clinics have physician assistants and registered nurses using the devices; other offices and clinics have cosmetologists and estheticians; while others have persons who hold no license administering the treatment. The Commission is concerned that unlicensed or inadequately trained persons are using prescriptive devices on patients. This is analogous to an unlicensed person dispensing prescription medications.

The Commission and its staff have received numerous inquiries in the past few years concerning these offices and clinics and the regulation of LLRP devices. Most of the questions concern who can use LLRP devices, whether such use can be delegated, and whether a physician has to be on site during the procedure. The Commission has also received complaints from patients and physicians that specific offices and clinics do not have appropriate safeguards to ensure patient safety. The Commission has received one complaint that a patient was injured by an untrained person using an LLRP device. Physicians have come to the Commission meetings to discuss the proposed rules and reported that they have treated patients who have had complications during treatment in offices and clinics with no physician supervision.

The Commission attempted to clarify this area by adopting a policy in 2003 entitled "The Use of Lasers in Skin Care and Treatment." Since the adoption of the policy, numerous non-laser devices have entered the market. The number of inquiries about the use of lasers and similar devices has increased since the policy took effect. The Commission wishes to clarify this area of medicine and set minimal standards for the use of such devices by physicians and physician assistants in our state. A number of other states have enacted statutes or adopted rules covering this area.

Briefly describe the proposed rule.

The proposed rule

- Defines Laser, Light, Radiofrequency, and Plasma Devices (hereafter LLRP devices) as medical devices (a) that use a laser, non-coherent light, intense pulsed light, radiofrequency, or plasma to topically penetrate skin and alter human tissue and (b) are classified by the Federal Food and Drug Administration as prescription devices;
- Provides that a physician or physician assistant must use an LLRP device in accordance with standard medical practice;
- States that the use of an LLRP device is the practice of medicine;
- Requires a physician or physician assistant to be appropriately trained in the physics, safety and techniques of using LLRP devices prior to using such a device, and to remain competent for as long as the device is used;
- Requires a physician or physician assistant to, prior to authorizing treatment with such a device, take the patient's medical history, perform an appropriate physical examination, make an appropriate diagnosis, recommend appropriate treatment, obtain the patient's informed consent (including informing the patient that a non-physician may operate the device), provide instructions for emergency and follow-up care, and prepare an appropriate medical record;
- Permits a physician or physician assistant to delegate use of the device to a properly trained and licensed professional under certain circumstances, but requires the physician or physician assistant to develop a specific protocol for the licensed professional to follow;
- Prohibits a physician from delegating an LLRP for use on globe of the eye;
- Requires the delegating physician to be on the immediate premises during the initial treatment to treat complications, if indicated;
- Permits the physician to be temporarily absent during treatment of patients with established treatment plans provided a local back-up physician agrees in writing to treat complications, is reachable by phone, and can see the patient within sixty minutes;
- Requires the delegating physician assistant to be on the premises during all treatment with an LLRP device.
- Provides that regardless of who operates the device, the physician is ultimately responsible for the safety of the patient.
- Requires the physician to establish a quality assurance program.

- Provides that the use of devices to penetrate and alter human tissue for a purpose other than to topically penetrate the skin constitutes surgery and is outside the scope of these rules.

Is a Significant Analysis required for this rule?

Yes.

A. Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

Under RCW 18.71.002, one of the purposes of the Commission is to regulate the competency and quality of professional health care providers under its jurisdiction by establishing consistent standards of practice. RCW 18.71.002 states that the Commission may develop rules to promote the delivery of quality health care to the residents of our state. There are no regulations or standards in our state for the use of these devices. The goal of the proposed rules is to promote patient safety by 1) clarifying this area of medicine and 2) by setting forth the conditions under which a physician or physician assistant may operate LLRP devices.

Currently, there are many offices and clinics around the state that use LLRP devices without the direct supervision of a physician or physician assistant. Some of the offices and clinics have a physician act as a "medical director." However, some of these offices and clinics do not require this physician to (a) be trained in the use of an LLRP device, (b) examine the patient to determine whether treatment with an LLRP device is appropriate for the patient's condition, (c) make sure the person administering the treatment is appropriately trained, (d) ensure the device is used in accordance with standard medical practice, (e) be on site for any treatments or have a back-up physician available to treat complications, (f) establish a quality assurance program, or (g) provide appropriate follow-up care. The rules specifically address each of these areas. This meets the objective of RCW 18.71.002 by promoting the delivery of safe health care to our residents.

B. Determine that the rule is needed to achieve these goals and objectives, and analyze alternatives to rulemaking and the consequences of not adopting the rule.

In 2003, the Commission adopted a Policy on the Use of Lasers in Skin Care and Treatment. Since then, numerous energy-based, prescription devices have entered the market. The field is rapidly changing. The Commission has learned that many more offices and clinics using LLRP devices have opened since 2003. Some of them are not complying with the policy.

The rules are needed because the Commission's current policy is outdated and does not have the force of law. The Commission cannot take action against a practitioner based solely on a violation of the policy. The rules set clear standards for the safe use of LLRP devices, thereby promoting the delivery of quality health care to the residents of our state.

If rules are not adopted, there will continue to be almost no regulation in this area. More and more offices and clinics will offer treatment with LLRP devices with little, if any, physician supervision. The number of unlicensed, inadequately trained and unsupervised persons administering potentially dangerous treatment to patients will increase. This will undoubtedly result in patients being harmed during treatment.

Unlike in other states, the only recourse for patients who are harmed by unlicensed persons will be to sue the unlicensed persons. Thus, the decisions on who uses the devices and under what circumstances will be determined by market economics or the civil court system, rather than by what is best for patient safety.

C. Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The clear benefit of the rule is enhanced safety of patients undergoing treatment with an LLRP device, as explained above. We can calculate quantitative benefits (costs averted / savings), i.e., the costs of injuries, pain and suffering as a result of using LLRP devices without the direct supervision of a physician or physician assistant. The data in this area is limited and not readily available. The Commission was informed of a young lady who received laser treatment at a mall salon in Washington to have some hair removed. The unlicensed individual treated the spot of hair with a laser. The spot was later diagnosed as malignant melanoma. Using a laser on a melanoma is only one of the potential risks when untrained or unsupervised individuals are deciding a medical treatment plan. Using a laser on a malignant melanoma may increase the rate at which the cancer spreads significantly and obscure the diagnosis and treatment of the malignant melanoma.

The proposed rules will affect medical offices and clinics in the state of Washington providing treatment with LLRP devices as applied to the skin. Although the proposed rules apply only to physicians and physician assistants, the proposed rules potentially could affect beauty salons, boutiques, spas and other small cosmetic businesses that use LLRP devices without physician or physician assistant supervision. If these businesses choose to comply with the rule, they will have to hire at minimum a physician assistant to provide supervision, examine each patient for a treatment plan according to an approved practice plan. If they do not comply with the rules, then there is the potential of DOH receiving a complaint of unlicensed practice which is investigated and may result in a Cease and Desist Order and fines.

There are potential costs due to the implementation of this rule. Practitioners who have an LLRP device in their clinics will have to be trained to use the device properly. Their staffs will have to be trained to use the device properly. A physician or physician assistant will have to see and examine each and every patient who wishes to undergo treatment with an LLRP device. The physician will have to contract with a back-up physician to provide treatment if there are complications. If a physician assistant delegates the use of an LLRP device, the physician assistant will have to be on site for each treatment. Each of these requirements may add to the cost of treatment with an LLRP device. On the other hand, the rules should decrease the cost of healthcare by reducing the severity or number of complications to patients.

The Commission believes improvement in the safety of patients undergoing treatment with LLRP devices will outweigh any potential increase in the cost of treatment.

D. Determine, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

Department staff worked closely with the Medical Commission, the Washington State Medical Association, persons using these devices, both licensed and non-licensed, and people associated with companies marketing devices to minimize the burden of these rules. In the course of these efforts, the rules went through numerous drafts.

One previous draft required the physician to be on site during each and every treatment with an LLRP device. This was modified to require the physician to be on site for the important initial treatment, to allow the initial treatment to continue if the physician is called away for an emergency, and to permit physicians to be temporarily absent during treatment for patients with established treatment plans so long as a back-up physician agrees to be reachable by phone and to respond to treat complications within sixty minutes.

Another proposal did not permit a physician assistant to delegate the use of the devices. The physician assistant rule was created to permit physician assistants to authorize the treatment and provide the same services as a physician, with the exception that the physician assistant must be on site for each and every treatment.

One person objected that the definition of devices was too broad, and should not include devices that use infrared, "or other forms of energy." The rules were modified to eliminate these devices from the scope of the rules.

There was objection to a provision in a prior draft that would have required the physician to use the device in accordance with the Intended Use Statement on file with the Food and Drug Administration. The objector believed this would preclude appropriate off-label uses of the device. The current rules merely require the physician to use the device "in accordance with standard medical practice."

The Commission has modified the proposed rules in response to feedback provided by persons who use these devices to make them less burdensome for those required to comply with it. It is noteworthy that the rules are less burdensome than the rules in most of the other states that regulate this area by permitting delegation to a broad range of licensed professionals, and not requiring on site supervision.

The current rules are the least burdensome to practitioners while still preserving necessary patient safety measures.

E. Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

F. Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities.

G. Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determines that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule does not differ from any applicable federal regulation or statute.

H. Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

The first section of the rule states that it applies to devices that have been classified by the Federal Food and Drug Administration as prescription devices. The FDA regulates the manufacture of medical devices and enforcement is geared toward manufacturers rather than end users. The FDA for the most part leaves the regulation of the use of the devices to state law.

The use of medical lasers in our state is largely unregulated. Under RCW 18.53.010(8) optometrists may use laser instruments for diagnostic purposes. Both WAC 246-855-010 (Osteopathic physicians' acupuncture assistants) and WAC 246-918-310 (Physician assistants-MQAC) define acupuncture as including laser puncture. WAC 246-855-090 prohibits an osteopathic physician acupuncture assistant from performing laser puncture. And WAC 246-918-230 (Physician assistants-MQAC) states that a number of procedures are considered the practice of medicine, including assisting surgeons in opening incisions by use of any surgical method including laser, scalpel, scissors or cautery.